ABSTRACT

Mutation and polymorphism of a gene in a particular region of an analyte nucleic acid is directly, reliably, and quickly detected, identified or quantitated in a simple operation from the specimen containing a minute amount of such analyte nucleic acid.

Such assay comprises the steps of amplifying the particular region of the analyte nucleic acid in the specimen to prepare a double stranded sample DNA; adding an excessive amount of said sample DNA to a labeled standard DNA comprising a double stranded nucleic acid having a site capable of binding to a solid support on one strand and a detectable label on the other strand to allow competitive hybridization to take place; and detecting the rehybridized labeled standard DNA by utilizing said detectable label and said site capable of binding to a solid support to thereby evaluate the degree of exchange of the complementary strands between said sample DNA and said labeled standard DNA for detecting the target DNA which is the same as said labeled standard DNA and which is present in said sample DNA; and the assay is characterized in that a detection limit for the target DNA which is the same as said labeled standard DNA and which is present in said sample DNA is preliminarily selected, and excessiveness of said sample DNA added to said labeled standard DNA in the competitive hybridization is selected in accordance with the thus selected detection limit. An assay kit for detecting, identifying or quantitating the mutation or polymorphism of a gene in accordance with such assay process is also provided.